

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

Rec'd PCT/PTO 09 FEB 2005

PCT

To:

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NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing
(day/month/year)

15.11.2004

Applicant's or agent's file reference
16579

IMPORTANT NOTIFICATION

International application No.
PCT/CA 03/01180

International filing date (day/month/year)
11.08.2003

Priority date (day/month/year)
09.08.2002

Applicant
OTTAWA HEALTH RESEARCH INSTITUTE et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international
preliminary examining authority:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Le Bolloch, C



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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

Applicant's or agent's file reference 16579		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA416)	
International application No. PCT/CA 03/01180	International filing date (day/month/year) 11.08.2003	Priority date (day/month/year) 09.08.2002	
International Patent Classification (IPC) or both national classification and IPC C08F220/54			
Applicant OTTAWA HEALTH RESEARCH INSTITUTE et al.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 8 sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the opinion II <input type="checkbox"/> Priority III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input checked="" type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application 			
Date of submission of the demand 09.03.2004		Date of completion of this report 15.11.2004	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer Clement, S Telephone No. +49 89 2399-8512 	

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/CA 03/01180**

I. Basis of the report

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*):

Description, Pages

1-49 as originally filed

Claims, Numbers

1-50 as originally filed

Drawings, Sheets

1/20-20/20 as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/CA 03/01180**

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).
- (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
- ☐ the entire international application,
 - ☒ claims Nos. 51-110
- because:
- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):
 - ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
 - ☒ the claims, or said claims Nos. 51-110 are so inadequately supported by the description that no meaningful opinion could be formed.
 - ☐ no international search report has been established for the said claims Nos.
2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:
- ☐ the written form has not been furnished or does not comply with the Standard.
 - ☐ the computer readable form has not been furnished or does not comply with the Standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:
- ☐ restricted the claims.
 - ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ neither restricted nor paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/CA 03/01180**

☒ not complied with for the following reasons:

see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☐ all parts.

☒ the parts relating to claims Nos. 1-50 .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-50
	No: Claims	
Inventive step (IS)	Yes: Claims	1-50
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-50
	No: Claims	

2. Citations and explanations

see separate sheet

Ad Section III:

An ocular implant comprising any synthetic polymer not defined goes beyond the content as originally filed (claims 51-64 and 65-80). An ocular implant comprising a lens body not defined goes beyond the content as originally filed (claim 81-110).

Thus, claims 51-110 do not fulfil the requirements of Art. 34 (2) (b) PCT.

Ad Section IV:

The ocular implant according to claims 51 to 110 and the terpolymer according to claim 1 are not so linked as to form a single general inventive concept.

Therefore, claims 1 to 110 do not fulfil the requirements of unity (Rule 13.1 PCT).

Ad Section V:

Due to the objections under sections III and IV, the examination on novelty, inventive step and industrial applicability is based on claims 1-50:

Novelty

EP-A-0 496 472 describes succinimide-containing polymers having recurring units derived from a) one or more ethylenically unsaturated oleophilic monomers (e.g. HEMA), b) one or more ethylenically unsaturated monomers having succinimidoxycarbonyl group (N-acryloyloxysuccinimide) and optionally c) one or more hydrophilic ethylenically unsaturated monomers (N-isopropylacrylamide). The copolymers are used in diagnostic methods and analytical elements (claims, page 2, 1. paragraph, page 4, lines 8-27). EP'472 neither discloses the selected terpolymer as claimed nor the molecular weight as claimed.

In WO 92/20721 (abstract) an UV-absorbent vinyl-resin is obtained by conducting the polymerisation of a monomer mixture containing a N-alkyl substituted (meth)acrylamide monomer and a monomer bearing a salt-forming group. The resin can be blended with a cosmetic base. Novelty is given.

US 2001/0003126 discloses a composition comprising a first synthetic polymer having nucleophilic groups (e.g. a synthetic polypeptide containing primary amino groups) and a second synthetic polymer having electrophilic groups (a hydrophobic polymer containing succinimidyl groups). The nucleophilic and electrophilic groups are capable of reacting to form covalent bonds between the synthetic polymers which result in formation of a three-dimensional matrix (claims). US'126 does not disclose the synthetic terpolymer as claimed. The composition may further comprise other components (e.g. proteins) and may be used for ophthalmic applications.

US-A-6,103,528 refers to gelling cell culture medium useful for forming a three dimensional matrix for cell culture in vitro, the gelling cell culture comprising a linear random copolymer ($M_w > 12,000$) of N,N-dialkyl substituted (meth)acrylamide monomer and a hydrophilic comonomer (e.g. 2-ethyl (meth) acrylate, acrylic acid) (claims, column 5, lines 13 to 32). US'528 does not disclose the terpolymer as claimed.

EP-A-0 230 898 discloses polyvinyl polymers (e.g. poly(6-(4-nitrobiphenyloxy)hexyl methacrylate) exhibiting nonlinear optical response. Novelty is given.

DE-A-36 26 160 discloses glue for paper on the basis of terpolymers of (meth)acrylamide, N-vinylimidazoline and N-vinylimidazole (K-value is 70 to 250). Novelty is given.

WO 01/32730 discloses an implantable biological device capable of encapsulating biologically active moieties (e.g. tissue), said device comprising an amphiphilic network membrane ($M_n = 2,000$ to $15,000$ g/mol) comprising the reaction product of:

a) a hydrophilic crosslinking agent and

b) hydrophilic comonomers;

a) is a (meth)acrylic acid (capping *one* arm of the three-arm telechelic polyisobutylene) which is derivatised to contain two pendant crosslinkable moieties (two (meth)acrylic acid ester groups of the entire residue of the three-arm telechelic PIB);

b) may be DMAm (claims; page 22, 1. paragraph). The pendant crosslinking groups do not contain free (meth) acrylic acid groups that are reactive with primary amines. Thus, novelty is given.

WO 93/10201 deals with a pressure-sensitive adhesive composition comprising a

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EXAMINATION REPORT - SEPARATE SHEET

International application No. PCT/CA 03/01180

copolymer of N-vinyl-2-pyrrolidone monomer and a comonomer selected from N,N-dimethylacrylamide, HEMA, (meth)acrylic acid, acrylamide, vinyl acetate and AMPS (claim 7). WO'201 does not disclose a terpolymer.

US-A-6,030,634 describes a thermally responsive gel composition comprising a thermosensitive polymer matrix comprising

- a) a poly(n-isopropylacrylamide) modified by copolymerization with a monomer selected from (meth)acrylate, (meth)acrylic acid, (meth)acrylamide, vinyl acetate and styrene and
- b) an interpenetrating hydrophilic polymer network comprising a protein.

The gel composition is used for repairing damaged tissues (claims). US'634 does not disclose the terpolymer as claimed, as it does not use the carboxylic acid comonomer derivatised to contain pendant crosslinkable moiety that are reactive with primary amines.

Inventive Step

None of the documents cited in the international search report suggests the terpolymer according to claim 1 in order to provide a biosynthetic matrix as a scaffold for tissue regeneration, for replacement of damaged or removed tissue in an animal or for coating surgical implants.

Thus, claims 1 to 50 fulfil the requirements of Art. 33 (3) PCT.

Industrial applicability

Claims 1 to 50 fulfil the requirements of Art. 33 (4) PCT).

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

WRITTEN OPINION (PCT Rule 66)

To:

White, Stephanie R.
OSLER HOSKIN & HARCOURT LLP
50 O'Connor Street
Suite 1500
Ottawa Ontario K1P 6L2
CANADA

Date of mailing (day/month/year)	18.05.2004
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Applicant's or agent's file reference
16579

REPLY DUE	within 3 month(s) from the above date of mailing
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International application No.
PCT/CA 03/01180

International filing date (day/month/year)
11.08.2003

Priority date (day/month/year)
09.08.2002

International Patent Classification (IPC) or both national classification and IPC
C08F220/54

Applicant
OTTAWA HEALTH RESEARCH INSTITUTE et al.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application
3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 09.12.2004

Name and mailing address of the international preliminary examining authority:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Clement, S

Formalities officer (incl. extension of time limits)
Le Bolloch, C.
Telephone No. +49 89 2399-8091



I. Basis of the opinion

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

Description, Pages

1-49 as originally filed

Claims, Numbers

1-50 as originally filed

Drawings, Sheets

1/20-20/20 as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

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4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	1 (no)
Inventive step (IS)	Claims	
Industrial applicability (IA)	Claims	1-50 (yes)

2. Citations and explanations**see separate sheet**

Ad Section V:

WO 01/32730 discloses an implantable biological device capable of encapsulating biologically active moieties (e.g. tissue), said device comprising an amphiphilic network membrane ($M_n = 2,000$ to $15,000$ g/mol) comprising the reaction product of:

- a) a hydrophilic crosslinking agent and
- b) hydrophilic comonomers;
- a) is a (meth)acrylic acid (capping *one* arm of the three-arm telechelic polyisobutylene) which is derivatised to contain two pendant crosslinkable moieties (two (meth)acrylic acid groups of the entire residue of the three-arm telechelic polyisobutylene);
- b) may be DMAAm (WO'730; claims; page 22, 1. paragraph).

Thus, present claim 1 is not novel over the disclosure of WO'730 (Art. 33 (2) PCT).